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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/770,653	01/29/2001	M. Pamela Griffin	10406/16	7814

7590

09/16/2002

UNIVERSITY OF VIRGINIA PATENT FOUNDATION
1224 WEST MAIN STREET
SUITE 1-110
CHARLOTTESVILLE, VA 22903

EXAMINER

OROPEZA, FRANCES P

ART UNIT

PAPER NUMBER

3762

DATE MAILED: 09/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/770,653

Applicant(s)

GRIFFIN ET AL.

Examiner

Frances P. Oropeza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-69 and 71-80 is/are pending in the application.
- 4a) Of the above claim(s) 50,51,58,63-67,74 and 77-80 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-49,52-57,59-62,68,69,71-73,75 and 76 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment under 37 CFR 1.11 received 6/18/02

1. Claims 39-69 and 71-80 are pending in this application.

Claim 70 was cancelled.

Claims 50, 51, 58, 63-67, 74 and 77-80 are drawn to a non-elected invention.

Claims 39, 41, 43, 47, 52, 55, 61, 68, 69 and 71-76 were amended by the Applicant to overcome the prior art of record, hence a new grounds of rejection is presented below.

Terminal Disclaimer

2. The terminal disclaimer filed on 6/18/02 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of United States Patent Nos. 6216032 and 6330469 has been reviewed and is accepted. The terminal disclaimer has been recorded.

The assignment document filed on 6/18/02 is acceptable as the documentary evidence required by 37 CFR 3.73. If the assignment document is not already recorded with the United States Patent and Trademark Office, it is suggested that the assignment document be submitted for recording among the Office assignment records. See 37 CFR 3.11 and MPEP § 302.

Claim Rejections - 35 USC § 112

3. Claim 45 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 45, "the data set" lacks antecedent basis. Claims 46-48, 50, 52 and 55 depend on claim 45 and also contain the phrase "the data set", hence review of these claims and amended as needed is suggested. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. Claims 39, 40, 42, 44-49, 52-56, 62, 68-69, 71-73 and 75-76 are rejected under 35 U.S.C. 102(b) as being anticipated by Gordon et al. (US4862361). Gordon et al. disclose use of heart rate power spectral analysis to monitor cardiovascular regulation as an indicator of physiological disturbance of the circulatory system homeostasis.

Gordon et al. teach a critically ill child may exhibit marked changes in heart rate, read to be heart rate variability, indicative of a major unrecognized pathology. When a child has a myocarditis (an inflammation of the muscular walls of the heart incidental to systemic disease), low frequency heart rate fluctuations are seen (c 4, l 54 - c 5, l 7). The systemic disease as disclosed by Gordon et al. may be a severe systemic infection (c 26, ll 42-51); it is inherent that severe systemic infections significant for an infant or neonate include necrotizing enterocolitis, pneumonia, sepsis and meningitis.

In this invention, the R-R intervals are measured, collecting 1024 points (a ten to the third order data set), and third moment and higher data set is created by a microprocessor using the mean heart rate to calculate a "tachometer waveform" and by using the respiratory peak within a peak and judging the value against a value of two standard deviations from the mean. (c 5, l 22 – c 6, l 7). A slew rate, read as the skew rate, is calculated using normalized data, a mean variance and a maximum of 10% of the heart rate waveform readings (c 16, l 64 – c 17, l 28). Stable and unstable graphic depictions of the parameters are shown in figures 10 and 11 (c 17, ll 29-41). Stable and unstable data sets graphically charted in figures 16, 17 and 18 show the distribution of heart rate variability data for 29 ill children monitored in a study (c 23, ll 35-51).

Claim Rejections - 35 USC § 103

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 41, 43, 57 and 59-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon et al. (US 4862361) in view of Schroepel et al. (US 6035233). As discussed in paragraph 4 of this action, Gordon et al. discloses the claimed invention except for, upon identification of heart rate variability, providing a diagnostic work-up for the illness, including a blood culture or a pathological specimen, and antibiotics to treat the infection.

Schroepel et al. disclose an implantable device responsive to heart rate variability and teach that, when heart rate variability is identified, it is known to selectively provide increasingly aggressive therapy regimes, beginning with a diagnostic work-up that would inherently include a blood culture and if additional signs of infection were present, such as an elevated temperature, a pathological specimen to identify any potential infection in the lungs or the spinal fluid. Drug therapy is a noted step in the therapy regime; antibiotics are inherent as the drug treatment for an infection (c 9, ll 3-45). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the heart rate power spectral analysis as taught by Gordon et al., with the diagnostic work-up for the illness, including a blood culture or a

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pathological specimen, and antibiotics as taught by Schroepel et al. to enable diagnosis of the potential fatal illness so effective treat may be rapidly undertaken to optimize the patient chances for recovery.

Other Prior Art Cited

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 4298011 to Mangurten et al. teaches the use of blood cultures to diagnosis infections.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fran Oropeza whose telephone number is (703) 605-4355. The examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 306-4520 for regular communication and (703) 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

FPO
9/3/02

[Signature]
JEFFREY R. JASTRZAB
PRIMARY EXAMINER

9/11/02